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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,773	03/23/2005	Tadashi Yoneda	Q72135	6335
23373	7590	10/12/2007		
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER UNDERDAHL, THANE E	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 10/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,773

Applicant(s)

YONEDA ET AL.

Examiner

Thane Underdahl

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/21/05 and 3/23/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Restriction/Election

Applicant's response to the restriction requirement without traverse filed on 7/26/2006 is acknowledged. The applicant elected Group I which includes claims 1-10. The elected species and the claims they include will now be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 2 are indefinite since it is unclear if the iturin A is externally added to the medium or is produced by the microbe. Clarification is required. In the interest of compact prosecution, the claim will read that the "microbes produce iturin A and its homologues at a concentration of 1.5 g/L in the medium". The term mass% is also unclear. In the interest of compact prosecution, the term will be interpreted as percent mass or % mass.

Claim 3 includes the phrase "substantially no ability to produce surfactin". This statement is unclear because it is unclear if the limitation is towards bacteria that does not inherently produce surfactin or could not be modified to produce the peptide of surfactin with modifications such as by recombinant DNA techniques. Clarification is required. In the interest of compact prosecution, the claim will read on any bacteria that does not explicitly produce surfactin.

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Claim 4 lists the mass percent of phosphates "in terms of K_2HPO_4 ". This is unclear since in terms of K_2HPO_4 can refer to the stoichiometric phosphate equivalents or simply the exclusive salt of di-potassium monohydrogen phosphate itself.

Clarification is required. In the interest of compact prosecution, the claim will read on any form of potassium phosphate in a medium.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over unpatentable over Phae et al. (J. of Fermentation and Bioengineering, 1991) and Tanaka et al. (U.S. Patent # 5470827).

These claims are drawn to a method for producing iturin A and its homologues in a liquid medium containing 2 % by mass or more of soybean powder or its extract to allow the microbe to produce iturin A and its homologues. The limitation that the microbe produce iturin A "at a concentration of 1.5 g/L" is an intended result and not an active step of the method. Any art disclosing the same steps as the proposed method will either inherently meet this limitation or obviously meet this limitation.

The microbe does not produce surfactin. The microbe is from the genus of *Bacillus* and specifically *Bacillus subtilis*. Claims 6 and 7 limit the *Bacillus subtilis* to the

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specific strain SD142 or its mutant. Claim 8 also lists additional nutrients in the medium such as maltose and glucose. Claim 4 limits that the medium contains 0 to 3 % by mass of phosphates such as K_2HPO_4 .

Phae et al. teach a *Bacillus subtilis* that produces and accumulates iturin A and its homologues in a liquid medium of glucose and polypepton with K_2HPO_4 (Phae, page 118, col 1). Phae et al. does not mention the production of surfactin in their culture. While Phae et al. does not disclose the particular yield of 1.5 g/L of the iturin A and its homologues since Phae et al. meets the steps of the method it would be obvious though routine optimization of reaction time and temperature as well as microbe concentration could meet this limitation (M.P.E.P. § 2144.05).

Also Phae et al. does not teach the specific cell lines of *Bacillus subtilis* limited in claims 6 and 7. However, the M.P.E.P. § 2144.09 states:

"A *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities"

Absent any evidence of criticality to the contrary, one of ordinary skill in the art would expect the same results for the *Bacillus subtilis* used by Phae et al. to that claimed by applicant.

What Phae et al. does not teach is the use of soybean powder or its extract to cultivate the *Bacillus* microbes. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Tanaka et al. Tanaka et al. teach a method of cultivating *Bacillus* in glucose like Phae et al. but also teach that soybean meal can be substituted for glucose as well (Tanaka,

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col 4, lines 9-25) in a medium that contains potassium phosphate (M.P.E.P. § 2144.06).

The Iturin A accumulated in the culture is isolated by Tanaka et al. and dried under a vacuum (Tanaka, Example 1, col 10, lines 53-55) so that it can be massed.

It would have been obvious to someone skilled in the art to combine the teachings of Phae et al. with Tanaka et al. Both share the same goal of producing and isolating iturin A and its homologues as well as using the same genus of bacteria to accomplish this task. Tanaka et al. even mentions that the *Bacillus subtilis*, like that used by Phae et al. does indeed produce iturin A. This provides the motivation and reasonable expectation of success to combine the teachings of Tanaka et al. and add soybean meal to the culture medium in the method of Phae et al.

Therefore the references listed above renders obvious claims 1-10.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

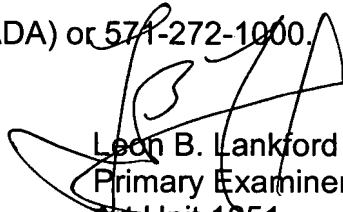
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651


Leon B. Lankford Jr
Primary Examiner
Art Unit 1651